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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/655,532	09/04/2003	Balbir S. Brar	SABRA.001CP1	5571

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EXAMINER

GHERBI, SUZETTE JAIME J

ART UNIT PAPER NUMBER

3738

DATE MAILED: 07/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/655,532	Applicant(s) BRAR ET AL.	
	Examiner Suzette J. Gherbi	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 42-73 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 42-73 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Applicant's RCE dated 7/1/05 has been received in application serial number 10/655,532.

Claim Objections

2. Claims 42-73 are objected to because of the following informalities: The status identifiers for the claims are incorrect. In order to avoid a Non-Compliance applicant must submit the proper status identifiers, for example claims 42, 48-73 should state [previously presented] because they were submitted in the amendment dated 11/15/04. Appropriate correction is required.

Claim Rejections - 35 USC § 102/103

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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5. Claims 42-43, 47-49, 53-57, 59, 61, 65-72 are rejected under 35 U.S.C. 102(e) as being anticipated by Falotico et al. 2003/0060877 or in the alternative under 35 USC 103(A) as obvious over Falotico et al. Falotico et al. discloses the invention as claimed noting figures 27-28 comprising: A tubular stent with a proximal end, distal end and center portion; a first drug layer (1002), a second drug layer (1004), a third drug layer (1006) and a fourth drug layer (1008); and a polymer barrier layer between each of the layers (see sections [0203-0204]; wherein the first drug is Corticosteroid or where in the third drug is Paclitaxel or wherein the third drug is Taxol (this is inherent because Falotico et al. states that the drugs can be used in *any* layer or combination) It is inherent that a fifth and sixth layer can be incorporated as stated in section [0205].; wherein the first drug consist of Indomethacin ; Cisplatin; [0070] ; wherein the polymer can be biodegradable [0201]; wherein the proximal end and the distal end diameter are greater than the diameter of the center portion (see figure 12); wherein the stent is balloon or self-expandable [0201]; wherein the drugs are time released [[0200]. The claimed phrase "*alternately provided repeatedly*" is being treated as a product by process limitation. As set forth in MPEP 2113, product by process claims are NOT limited to the manipulations of the recited steps, only to the structure implied by the steps. Once a product appearing to be substantially the same or similar is found, a 35 USC 102/103 rejection may be made and the burden is shifted to applicant to show an unobvious differences. See MPEP 2113. Thus even though Falotico et al. is silent as to "*alternately provided repeatedly*" it appears that the product of Falotico et al. would be the same or similar as that claimed.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 44-46, 50-52, 60, 62-64, 73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Falotico et al. in view of Wnendt et al. 2004/0117008. Falotico et al. has been disclosed above however Falotico et al. does not disclose the drug Dexamethasone. Wnendt et al. teaches a stent with drug delivery properties that utilizes the drug Dexamethasone (see [0069]). It would have been obvious to one having ordinary skill in the art at the time the invention was made to take the stent of Falotico et al. and utilize the drug Dexamethasone because it would be another drug that would provide immunosuppressants or antibiotic and is a matter of design choice.

8. Claim 58 rejected under 35 U.S.C. 103(a) as being unpatentable over Falotico et al. in view of Palasis et al. 6,369,039. Falotico et al. has been disclosed above however Falotico et al. does not disclose Polybutylene as one of the polymers. Palasis et al. teaches a drug delivery stent that utilizes Polybutylene. It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize

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Polybutylene as one of the polymers because it is a well know polymer in the use of tubular implants.

Response to Arguments

9. Applicant's arguments filed 7/1/05 have been fully considered but they are not persuasive. Applicant has pointed out that the specification discloses the phrase "repeated cycles in section [0142] and "alternative cycles" in section [0144]. The examiner has reviewed this section and agrees that they are present however notes that no definition has been assigned to the phrase therefore the phrases will be interpreted as presented in the specification.

10. Applicant contends that Falotico does not teach every element of the claims under 102(e) specifically (see page 4 of response) ... "Falotico does not teach or suggest among other things, therapeutic agents alternately provided repeatedly on the stent." Applicant further debates this phraseology throughout the 103 rejections.

11. It is the examiners opinion that the office action is deemed proper. Applicant first contends that these are not product by process claims. It is pointed out to applicant that the manner in which the claims are worded do make them product by process. For example the phrase "alternately provided repeatedly" can be interpreted as applying therapeutics in several manners i.e. not just in layers, but also in different locations along the stent. Also, the terms "alternately" can be interpreted as an "optionally"

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limitation and are therefore viewed as a process do to the functionality. Please see MPEP 2173.05(h).

12. It is further pointed out to applicant that Falotico does disclose the limitations of alternately repeating. Turning to section [0104, line 18], Falotico states”

*“**Alternately**, the second layer could comprise a different drug to provide **sequential drug delivery**. Multiple layers of different drugs could be provided by **alternating** layers of the first one polyfluoro copolymer then the other. As will be readily appreciated by those skilled in the art **numerous layering approaches may be used to provide the desired drug delivery.**”*

13. This phrase and the terms are synonymous to the current claim limitations wherein sequential equates to repeatedly and alternating equals alternately. Falotico discloses an invention, which is parallel to applicant's invention, and the layers of polymers and drugs can all be manipulated in a variety of manner for the exact same purpose as applicant's invention and that is for inhibiting and preventing restenosis.

Conclusion

14. This is an RCE of applicant's earlier Application No. 10/655,532. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


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15. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzette J. Jackson whose work schedule is Monday-Friday 9-6:30 off every other Friday and whose telephone number is 571-272-4751.

17. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306.

18. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.


Suzette J-J Gherbi
12 July 2005